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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/840,041 | 05/06/2004 | Fabrizio Alessandro Maspero | 1032553-000059 | 7765 |

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BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
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| EXAMINER |
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RAMANA, ANURADHA

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| ART UNIT | PAPER NUMBER |
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3775

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

05/10/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/840,041 | Applicant(s) MASPERO ET AL. | |
| | Examiner Anu Ramana | Art Unit 3775 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15, 16 and 41-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15, 16 and 41-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 13, 2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 15-16 and 41-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1, 41 and 43, the recitation "bound to each other by adhesion between the biocompatible polymer disposed on adjacent granules" is not consistent with Applicant's disclosure, as originally filed. The claims appear to imply discrete polymer-coated particles held together by adhesion which is not consistent with Applicant's disclosure. Fig. 1B of Applicant's disclosure shows polymer-coated particles held in a matrix 16.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41-46, 51-55, 63 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Ricci et al. (US 6,770,695).

Ricci et al. disclose an implantable or moldable composition including: synthetic calcium sulfate particles having a size greater than 20 microns; a biocompatible or biodegradable polymeric coating on the particles wherein the polymer is any type of resorbable polymer (for e.g. polylactides, polydixanones etc.), the weight of the polymer is about 0.1% to about 50% by weight and the thickness of the polymeric coating is 0.5 microns to 100 microns; a plasticizer such as acetone; and a setting agent such as water or saline (col. 3, lines 11-28 and col. 4, lines 5-47). Once solidified in a bone defect, the Ricci et al. composition forms a composite matrix with pores filled with air.

Regarding claim 55, it is noted that Ricci et al. disclose particles having a size (underline, emphasis added) greater than 20 microns, i.e., regularly-sized particles.

Regarding claims 63 and 64, it is noted that Ricci et al. discloses a specific value of particle size, i.e., a size greater than 20 microns, which is within the claimed ranges "of about greater than 10 microns to about 2000 microns" and "of about 100 microns to about 500 microns". It is noted that a specific example in the prior art which is within a claimed range anticipates the range. MPEP 2131.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-9, 11-12, 16, 47-50, and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. (US 6770695).

Ricci et al. disclose an implantable or moldable composition including: synthetic calcium sulfate particles having a size greater than 20 microns; a biocompatible or biodegradable polymeric coating on the particles wherein the polymer is any type of resorbable polymer (for e.g. polylactides, polydixanones etc.), the weight of the polymer is about 0.1% to about 50% by weight and the thickness of the polymeric coating is 0.5 microns to 100 microns; a plasticizer such as acetone; and a setting agent such as water or saline (col. 3, lines 11-28 and col. 4, lines 5-47).

Ricci et al. disclose particles with a size greater than 20 microns. Ricci et al. also disclose the weight of the polymer to be about 0.1% to about 50% by weight.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided particles with sizes in a range of about 100 microns to about 4000 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided polymer in a range of about 4% to about 20% by weight, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a polymeric coating thickness in a range of about 1 micron to about 300 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Evans et al. (US 7241316).

Ricci et al. disclose all elements of the claimed invention except for alternate types of biocompatible ceramics.

Evans et al. teach the use of biocompatible ceramics such as various calcium phosphate salts (col. 20, lines 21-51).

The substitution of one known ceramic (various types of calcium phosphate) for another known ceramic (calcium sulfate as disclosed by Ricci et al.) would have been obvious to one of ordinary skill in the art at the time of the invention since this amounts to simple substitution of one known ceramic for another and would have yielded predictable results, namely, a biocompatible, implantable composition.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Meredith (US 7001551).

Ricci et al. disclose all elements of the claimed invention except for a biologically active substance.

It is well known to use a biologically active substance such as a growth factor in an implantable composition to enhance bone growth into a bone defect, as evidenced by Meredith (col. 9, lines 53-67 and col. 10, lines 1-26).

Therefore, it would have been recognized by one of ordinary skill in the art that applying the known technique of providing a biologically active substance such as a growth factor, taught by Meredith, in the Ricci et al. implantable composition would have yielded predictable results, i.e., improved repair of a bone defect by enhancing bone growth to seal the defect.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Smestad (US 4430760).

Ricci et al. disclose all elements of the claimed invention except for the use of a microporous membrane.

It is well known to use a porous casing or membrane to contain filling material used to repair a bone defect, as evidenced by Smestad (col. 2, lines 57-68 and col. 3, lines 1-57).

Therefore, it would have been recognized by one of ordinary skill in the art that applying the known technique of providing a porous casing, as taught by Smestad, to hold the Ricci et al. material would have yielded predictable results, i.e., containment having a desired shape and size for sealing a bone defect.

Response to Arguments

Applicant's arguments have been fully considered by the examiner but are not persuasive for the following reasons.

Upon further consideration and based on Applicant's arguments, the Examiner is withdrawing the rejections under 35 USC 102(e) over Evans et al.

Regarding the rejections under 35 U.S.C. 102(e) over Ricci et al., it is noted that Ricci et al. clearly disclose that when the calcium sulfate particles are mixed with resorbable polymer, a coating is formed on the particles. It is the Examiner's position that when a plasticizer such as acetone is mixed in with the polymer-coated particles of Ricci et al., some of the particles would be bound by adhesion between the polymeric coatings on the particles.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

March 28, 2011

/Anu Ramana/

Primary Examiner, Art Unit 3775